UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,609	08/07/2006	Hisakazu Katsuki	KATSUKI2	8366

1444 7590 12/29/2009

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
12/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,609	KATSUKI ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,12-14,17 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,12-14,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action

Claims 10, 12-14, 17-18 are pending. Amendments are entered. No claim is allowed.

Summary of this Office Action dated Wednesday December 16, 2009

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. 35 USC § 112 (1) Written Description and New Matter Rejection
5. 35 USC § 112 (2) Rejection
6. 35 USC § 102 (b) Rejections
7. 35 USC § 103(a) Obviousness Rejection
8. Response to Remarks
9. Conclusion
10. Communication

Applicants' arguments, filed 10/14/2009, have been fully considered. Rejections not reiterated from previous office actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b).

See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 12-13 and 18 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. There is no description or guidance for suppressing the "generation" in the specification as has been claimed. There is no description of the "under shading" as claimed in claim 13. Applicant is kindly requested to explain this issue.

4. Shading is not defined in the specification. It can be at any temperature or conditions.

5. Claim 18 is new claim and is considered "new matter". There is no method for "improvement" in the disclosure.

Applicant had no possession of the claimed subject matter. Specification contains no example, description, teaching or guidance so that one skilled in the art to make and use the invention as has been presently claimed.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See *In re Kaslow*, 707 F 2d 1366, 1375 (Fed. Cir. 1983).

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him.

See *Genetech,* 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

Applicant is kindly requested to explain the issue.

See MPEP 2163.06

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12 and 13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. It is unclear what is intended by “generation” in claim 12?

4. It is unclear what is intended by "shading" in claim 13.

5. In claim 18 it is unclear what the “improvement” is?

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 10, 14, 17 and 18 rejected under 35 U.S.C. 102(b) as being anticipated by YAMAUCHI, Tsuyoshi (US 6,448,421). The reference discloses preparation and purification of ED-71 which embraces Applicant’s claimed invention. THE reference discloses the preparation of ED-71 of formula I and tachysterol of formula III and in column 4. The reference further discloses that these compounds are contained in reaction mixture obtained by ultraviolet light radiation and the subsequent thermal isomerization reaction of the pro-form of

ED_71. See lines 15-19 in column 5. See also compound IX which is ED-71 in column 8. See also examples 1 and 2 where the synthesis of ED-71 has been described and pro-form and perform of ED-71 are disclosed.

8. The reference also discloses that that the tachy and lumi forms which are analogues of ED-71 and pro-form of ED-71, respectively, are novel compounds and are useful **for a test or analysis which may be carried out in the synthesis of a vitamin D derivative**. See lines 37-41 in column 19 See tables 1-5 in column 17-19 where the products are disclosed.

9. Therefore it is evident that the reference discloses all the degradation products as has been claimed. Further, the composition and all the claimed invention is **directly or inherently** disclosed by the reference.

Claims 10, 14, 17 and 18 rejected under 35 U.S.C. 102(b) as anticipated by MIYOMOTO (Chem. Pharm. Bull) and MIYAMOTO et al. (US Patent 4,666,634). The presently claimed invention is inherently disclosed by the references.

MIYOMOTO (Chem. Pharm. Bull) teaches preparation of vitamin D compounds including ED-71. Various steps and intermediates are taught. See chart 2 on page 1111, experimental section on pages 1112 and 1113 are taught.

MYOMOTO in US '634 teach synthesis of ED 71, see the entire document especially example 13 and process for preparing compound and intermediates. See columns 4-9 where intermediates and ED-71 were prepared.

The references cited above inherently disclose presently claimed invention.

35 USC § 103(a) Obviousness Rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 12-14, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over YAMAUCHI, Tsuyoshi (US 6,448,421). MIYAMOTO et al. (US Patent 4,666,634 and MIYOMOTO, Chem. Pharm. Bull), JP Publication number: 05-004925, Publication Number: 06-087750 and CHEN et al. (WO 03/047595).

10. The references teach the composition, preparation and purification of ED-71 which embraces Applicant's claimed invention.

11. YAMAUCHI teaches the preparation of ED-71 of formula I and tachysterol of formula III and in column 4. The reference further discloses that these

compounds are contained in reaction mixture obtained by ultraviolet light radiation and the subsequent thermal isomerization reaction of the pro-form of ED_71. See lines 15-19 in column 5. See also compound IX which is ED-71 in column 8. See also examples 1 and 2 where the synthesis of ED-71 has been described and pro-form and perform of ED-71 are disclosed.

12. The reference also teaches that that the tachy and lumi forms which are analogues of ED-71 and pro-form of ED-71, respectively, are novel compounds and are useful **for a test or analysis which may be carried out in the synthesis of a vitamin D derivative**. See lines 37-41 in column 19 See tables 1-5 in column 17-19 where the products are disclosed.

13. The reference discloses all the degradation products as has been claimed. Further, the composition and all the claimed invention is taught by the reference.

MIYOMOTO (Chem. Pharm. Bull) teaches preparation of vitamin D compounds including ED-71. Various steps and intermediates are taught. See chart 2 on page 1111, experimental section on pages 1112 and 1113 are taught. MYOMOTO in US '634 teach synthesis of ED 71, see the entire document especially example 13 and process for preparing compound and intermediates. See columns 4-9 where intermediates and ED-71 were prepared.

CHEN et al teaches pharmaceutical compositions comprising an active vitamin D compound in emulsion pre-concentrate formulations, as well as emulsions and sub-micron droplet emulsions produced therefrom. The compositions comprise a lipophilic phase component, one or more surfactants, and an active vitamin D compound. The compositions may optionally further comprises a hydrophilic phase component. See the entire document especially [0056] where antioxidant BHA, BHT and **tocopherols** are taught. See [0036] and [0037] where fish oil, vegetable oils triglyceride are taught. The reference teaches active vitamin D compounds [0055] including calcitriol where antioxidants are used. The reference teaches antioxidants such as ascorbyl palmitate, butyl hydroxyl anisole (BHA), butyl hydroxyl toluene (BHT) and tocopherols **and d-tocopherols (vitamin E)** are taught (present specification discloses all these antioxidants). For the dosage see [0060].

PATENT ABSTRACTS OF JAPAN
(11)Publication number :
05-004925
(43)Date of publication of application : 14.01.1993
The reference teaches the use of tocopherol for stability "PURPOSE: To provide a soft capsule preparation improved in the storage stability of alpha calcidiol in an extremely good state.
CONSTITUTION: An alpha calcidiol soft capsule preparation comprises alpha calcidiol and a medium chain aliphatic trig1yceride solution received in a gelatin Shell containing titanium oxide and g1ycerol, the medium chain aliphatic trig1yceride solution containin6 dibutylhydroxytoluene and dl-a-tocopherol in a

weight ratio of 1:1 in a total weight of at least 0.005 wt.%".

PATENT ABSTRACTS OF JAPAN

(11)Publication number :
06-087750

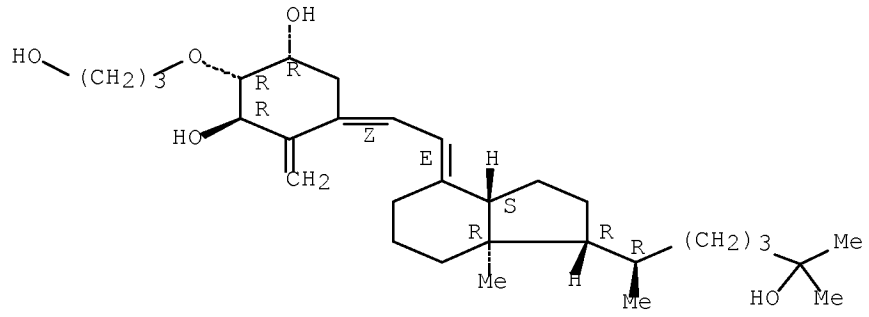
KAWASE YASUKO
(54) MEDICINE COMPOSITION
(57)Abstract:
The reference teaches that by adding tocopherol as a stabilizer vitamin D as an active agent can be prevented from dedecoposing and maintain stability.
"PURPOSE: To obtain a medicine composition useful for treating osteoporosis, vitamin D dysbolism, chronic renal insufficiency, etc., comprising la,25-dihydroxycholecalciferol and a tocopherol.
CONSTITUTION: A medicine composition comprises 0.00001-0.001wt.% 1a,25-dihydroxycholecalciferol and 0.01-5wt.% tocopherol. The medicine composition is properly mixed with various additives useful for pharmaceutical preparation of common medicines such as crystalline cellulose, lactose, starch, mannitol, silicic anhydride, hydroxypropyl cellulose, magnesium stearate and anhydrous ethanol and pharmaceutically manufactured. The medicine composition can pharmaceutically be manufactured into a dosage form such as tablet, granule, fine granule or capsule. By addition of a tocopherol as a stabilizer, 1a,25-dihydroxycholecalciferol as an active ingredient can be prevented from decomposing and maintained stability"..

See both 5E, 7E and 5Z, 7E are known. The structures are disclosed as follows.

104121-92-8 REGISTRY
ED Entered STN: 06 Sep 1986
CN 1,3-Cyclohexanediol, 2-(3-hydroxypropoxy)-4-methylene-5-[(2E)-2-[(1R,3aS,7aR)-octahydro-1-[(1R)-5-hydroxy-1,5-dimethylhexyl]-7a-methyl-

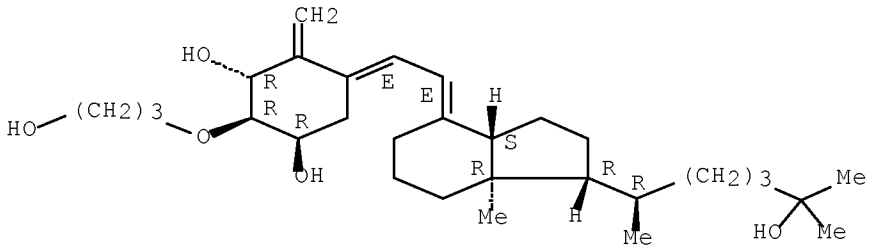
4H-
inden-4-ylidene]ethylidene]-, (1R,2R,3R,5Z)- (CA INDEX NAME)
OTHER CA INDEX NAMES:
CN 9,10-Secocholesta-5,7,10(19)-triene-1,3,25-triol, 2-(3-hydroxypropoxy)-, (1α,2β,3β,5Z,7E)- (9CI)
OTHER NAMES:
CN 2β-(3-Hydroxypropoxy)-1α,25-dihydroxyvitamin D3
CN ED 71
CN Eldecalcitol

Absolute stereochemistry. Rotation (+).
Double bond geometry as shown.



L15 ANSWER 1 OF 1 REGISTRY COPYRIGHT 2008 ACS on STN
RN 86196-34-1 REGISTRY
ED Entered STN: 29 Aug 2005
CN 9,10-Secocholesta-5,7,10(19)-triene-1,3,25-triol, 2-(3-hydroxypropoxy)-, (1α,2β,3β,5E,7E)- (9CI) (CA INDEX NAME)
FS STEREOSEARCH
MF C30 H50 O5
SR CA
LC STN Files: CA, CAPLUS, USPATFULL

Absolute stereochemistry.
Double bond geometry as shown.



It would have been obvious to one skilled in the art to prepare additional beneficial preparation containing ED-71 and its intermediates or degradation products by using the ingredients, fat and oil and an antioxidant alpha tocopherol because all the compounds as claimed are taught by the references and use of tocopherol as good stabilizer has been taught by the JP abstracts. The degradation product would be present in composition containing ED-71. Prior art teach the degradation product.

Motivation has been provided by the prior art to prepare composition of active vitamin D compounds such as calcitriol and ED-71. Motivation to combine the teachings of CHEN, JP abstracts and MYOMOTO would have been obvious at the time of invention was filed. Even in a case where the reference does not teach the same use of the composition, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau,* 57 USPQ 324; *Ex parte Douros,* 163 USPQ 667; and *In re Craige,* 89 USPQ 393.

The discovery of a new action underlying a known process does not make it patentable. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. Also, it is irrelevant that the prior art observers did not recognize the property or function of the disputed claim; if the prior art inherently possessed that characteristic, it anticipates. See *Verdeegal Brothers, lnc. v. Union Oil Co. of Cal.,* 814 F.2d 628, 633, 2 U.S.P.Q.2d 1051, 1054 (Fed. Cir. 1987). This is believed to be applicable here because anticipation is the epitome of obviousness.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Response to Remarks and Declaration

- The declaration filed by Applicants and amended claim limit the antioxidant to dl-alpha-tocopherol now. Tocopherol has been used by the reference. Further JP-Pub. No. 06-087750 teaches that tocopherol is a stabilizer and is used to stabilize the composition. Applicant is trying to establish that use of tocopherol in composition is unexpected for suppressing the degradation products. This is known in prior art. The rejection is maintained.

- Examiner disagree that WO reference does not teach "antioxidants" because the reference teaches ascorbyl palmitate, butyl hydroxyl anisole (BHA), butyl hydroxyl toluene (BHT) and **tocopherols and d-tocopherols (vitamin E)** are taught. Present specification discloses all these antioxidants. Furthermore, the term "comprising" in claims allows other components can be added. Other antioxidants can be added as in claim 12. And other componenets can be added in claim 10. Prior art does teach the composition which contains the products as in claim 10, 12, 13, 14 and 16.
- Applicant argue that trans ED-71 is more active than ED-71 in differentiation. However, there is no mention in the specification that this compound is useful other than synthesis. Applicant arguments cannot take the evidence. "The ED-71 preparation of the present invention makes it possible to provide a pharmaceutical formulation capable of suppressing the generation of a degradation product of ED-71. The trans form of ED-71 is useful as a standard in the analysis of ED-71 preparation and is also useful as a material for the synthesis of various types of vitamin D- based compounds". See paragraph [0095]. Furthermore the abstract of the invention as disclosed in the publication on STN further supports examiners point that the trans compounds is the degradation product and Applicants are

trying to suppress the formation of this compound. The publish abstract (DN 143:199944, CAPLUS, abstract of WO 200574943) is "Disclosed is a pharmaceutical preparation which can inhibit (5Z,7E)-(1R,2R,3R)-2-(3-hydroxypropoxy)-9,10-secocholesta-5,7,10(19)- triene-1,3,25-triol (ED-71) from yielding tachysterol and the trans isomer, which are major products of the decomposition of ED-71 during storage at room temperature The pharmaceutical preparation comprises (5Z,7E)-(1R,2R,3R)-2-(3-hydroxypropoxy)-9,10-secocholesta-5,7,10(19)-triene-1,3,25-triol, a fat, and an antioxidant. For example, a composition containing ED-71, ethanol 1.3, dibutylhydroxytoluene (BHT) 0.02, and medium-chain triglyceride balance to 100 % was filled in a gelatin soft capsule shell". Claim 13 of the present invention is drawn to 1R,2R)-1,25-dihydroxy-2-(3'-hydroxypropoxy)-cholecalciferol; 2.beta.-(3'-hydroxypropoxy)-(1.alpha.,3.beta.,5Z,7E)-9,10-secocholesta-5,7 ,10(19)-triene-1,3,25-triol (ED-71).

]0092] As can be seen from Table 8, all the antioxidants used remarkably suppressed **tachysterol** and trans forms. [0093]

Example 5: (page 34), **dl-a-tocopherol** (manufactured by Wako Pure Chemical Industries, Ltd.), **dibutylhydroxytoluene** (manufactured by Wako Pure Chemical Industries, Ltd.), **butylhydroxyanisole** (manufactured by Wako Pure Chemical Industries, Ltd.),

Furthermore, the arguments is that trans is better that ED-71, however examiner notes that preparation as claimed are not drawn to trans ED-71.

The trans ED-71 is a degradation product and is present in ED-71 in a very small quantity. **The preparation taught by WO reference contains all the ingredients as claimed. Nothing new was found in the preparation of ED-71. Preparation of trans isomer of ED-71 was not disclosed and was not intended in the disclosure. It is a degradation produce of ED-71.**

ADVANTAGE OF THE INVENTION as disclosed in present specification

[0019] The ED-71 preparation of the present invention makes it possible to provide a pharmaceutical formulation capable of suppressing the generation of a degradation product of ED-71. The trans form of ED-71 can be used both as a standard in the analysis of an ED-71 preparation and as a material for the synthesis of various types of vitamin D- based compounds.

Applicant further argue that new claim 13 specifies that (SE, TE)-(IR, 2R, 3R)-2-(3-hydroxypropoxy)-9,10-secocholesta-5,7,10(19)-triene-l,3,25- triol (trans form of

ED-71) is an **isolated** compound. Examiner believes that the chemical structure of the compound is the same no matter it has been isolated or synthesized.

Furthermore, it has also been decided that "when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." Id. at 1742

See also KSR Supreme Court of United States Decision KSR INTERNATIONAL CO. v. TELEFLEX INC. et al. No. 04-1350; 550 U.S.-, 82

USPQ 2d 1385 (2007) where it states that (1) “However, the issue is not whether a person skilled in the art had the motivation to combine the electronic control with an adjustable pedal assembly, but whether a person skilled in the art had the motivation to attach the electronic control to the support bracket of pedal assembly”. (2) "the results of ordinary innovation are not the subject of exclusive rights under the patent laws". In the present case the as claimed would have been obvious to one skilled in the art at the time the invention was made.

In summary Examiner concludes that claims and specification does not provide any new concept, improvements for the reasons cited above. To emphasize this point Examiner would like to refer Applicants to Genetech, 108 F.3d at 1366 and Brenner 383 U.S. 519, 536, 148 USPQ 689, 696 (1966)” which states that “a patent is not a hunting license. It is not a reward for research, but a compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague limitations of general ideas that may or may not be workable.”

CONCLUSION

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612